

REMARKS

The Applicant respectfully requests that the pending claims 31-40, 43-60, 63-80 and 83-85 be cancelled from the application. The remaining claims 23-30, have not been amended for purposes of this response.

Applicant's representative Sarah Vaz thanks Examiner Choi for agreeing to a telephone interview on May 17, 2005, wherein Examiner Choi agreed that Claims 23-30 are entitled to the May 27, 1999 filing date, and therefore predate U.S. Patent Nos. 6,258,846 to Hermelin et al. and 6,346,231 to Opheim.

In response to the Office Action dated March 18, 2005, Applicant enters the following remarks:

Rejection under 35 U.S.C. § 112:

Claims 63 and 71 have been cancelled without prejudice, therefore the rejection of said claims is moot.

Rejection under 35 U.S.C. § 103(a):

The Examiner has previously rejected the then pending claims under 35 U.S.C. 103(a) as being unpatentable over Hermelin et al. (U.S. Patent No. 6,258,846) or Abbruzzese (U.S. Patent No. 6,077,828), each in view of acknowledged prior art Opheim (U.S. Patent No. 6,346,231), Manufacturing Chemist & Aerosol News and Cuca (U.S. Patent No. 4,656,231.) In noting that the application is only an indirect continuation in part, the Examiner asserted that the Applicant was not entitled to the May 27, 1999 filing date of Serial No. 09/320,559 "to the extent the claims contain the omega fatty acids, said claims are not entitled to the May 27, 1999 filing date...." (See Office Action dated June 17, 2004, page 4, fourth paragraph.) By retaining only

Claims 23-30, applicant has cancelled all claims that reference precursor, derivative or omega fatty acids.

During the telephone interview of May 17, 2005, the examiner agreed that the remaining Claims 23-30 are fully disclosed and enabled in the 09/320,559 application, and are therefore entitled to the May 27, 1999 filing date.

Previously Presented Claims Supported by the 09/320559 Application

| Claim # in 10/714,156 | Supporting Language in 09/320559 | Comments |
|-----------------------|---|--|
| 23 | <u>Fatty Acids</u> : Page 33, Lines 16-24. <u>Calcium Compounds</u> : Page 33, Lines 1-15. <u>Soft Gelatin Shell</u> : Page 27, Lines 7-24. Page 28, Lines 1-9 | |
| 24, 25 | <u>Fatty acids from various listed marine sources</u> : Page 33, Line 24. Page 34, Lines 8-12. Page 36, Lines 15, 20, 21. | All specific fish oils in claim 25 are listed on Page 34 of '559 |
| 26 | <u>Fatty acids form various listed plant sources</u> : Page 33, Line 24. Page 34, Lines 1-7. Page 36, Lines 15-20. | |
| 27, | <u>Fatty acids form various listed plant sources</u> : Page 33, Line 24. Page 34, Lines 1-7. Page 36, Lines 15-20. | All specific plant oils in claim 27 are listed on Page 34 & 36 of '559. |
| 28 | <u>Calcium compounds</u> : Page 33, Lines 1-15. | All specific calcium compounds in claim 28 are listed on Page 33 of '559 |
| 29,30: | <u>Calcium Compounds</u> : Page 45, Table II , Formula I and Formula II | |

As noted previously, Serial No. 09/320, 559 with a filing date of May 27, 1999, precedes all but the Abbruzzese, Cuca and Manufacturing Chemist and Aerosol news references cited by the Examiner as a basis for rejection under 35U.S.C.103(a). Although the Abbruzzese reference does describe some of the components specified in the '559 application, it claims a liquid

preparation, stating that some of the components may be introduced to the patient through the use of capsules. There is no reference to soft gelatin capsules. Moreover, all of the compositions outlined in Abbruzzese target patients suffering from cancer-related cachexia and/or anorexia and include high levels of amino acids, (which it can be argued are contraindicated as dietary supplements for the pregnant and nursing women) as well as other components. It is respectfully submitted that without impermissible hindsight based on the instant application, there can be no motivation to 1) look to a cachexia/anorexia treatment, 2) pick and choose from the components, and then 3) substitute fish oil for the omega fatty acids claimed in Abbruzzese, in order to formulate a nutritional supplement for pregnant or nursing mothers.

The Cuca reference teaches an antacid comprised of concentrated calcium suspensions in a Polyethylene Glycol (PEG) vehicle for soft gelatin capsule encapsulation. In contrast to the Cuca reference, the '559 application teaches the suspension of calcium and other nutrients in plant and marine oils for soft gelatin capsule encapsulation. Since the physical, chemical and biological properties of PEG are distinct from those of the fish and marine oils specified in the '559 application, we argue that the substitution of plant and marine oils for PEG as calcium suspension vehicles is non-obvious.

Finally, the Manufacturing Chemist and Aerosol news citation simply discloses omega-3-fatty acid encapsulation in soft gelatin tablets. The examiner has repeatedly argued that the '559 application does not disclose or enable the use of omega-3's, and claims referring to omega fatty acids have been cancelled. The applicant concludes that the compositions and methods claimed in this application would not have been obvious to an individual of ordinary skill in the art based on the collective teachings of Abbruzzese, Cuca, and Manufacturing Chemist and Aerosol News

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references, if for no other reason than none of these references discloses, teaches or suggests a supplement of any kind for pregnant or nursing mothers.

If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard.

Respectfully submitted,

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